UNC SOM GUIDELINES FOR HUMAN SUBJECTS RESEARCH IN THE CONTEXT OF COVID-19

<u>Please note, updates may be made frequently. Always reference the CRSO website to ensure you are working under the current version.</u>

www.med.unc.edu/crso

Version Date: January 4, 2021

Summary of Changes

Brief Description of Change	Reason for Change	Date
Added requirement to wear eye protection (in addition to mask) when interacting with subjects who cannot reliably wear masks	To maintain alignment with UNC Health policies	5/28/2020
Removed all requirements related to measuring temperature (for participants and employees)	To maintain alignment with UNC Health policies	6/5/2020
Added resources: 1) COVID-19 information review documentation template 2) Participant visit checklist template	Provide additional resources	6/19/2020
Removed requirements to establish designated work "windows." Building occupancy must remain at <50% at all times.	To allow more flexibility for conducting on-campus work	8/1/2020
Removed requirement for advance wellness screenings for study visits that occur in the context of clinical visits (provided that the participant has confirmed his/her willingness to initiate or continue study activities). Removed reference to colored dots used to indicate wellness screenings completed for employees.	To maintain alignment with UNC Health workflows and reduce burden for clinically-indicated visits. To maintain alignment with UNC Health policies	8/17/2020
Added recommendation to wear eye protection in addition to face masks for all participant encounters and in small indoor areas with others.	To protect personnel and reduce chances of accidental COVID exposure	8/21/2020
Added requirement to wear eye protection in addition to face masks for all participant/patient encounters.	To maintain alignment with UNC Health policies	9/9/2020
Removed requirement for studies involving direct contact to undergo review by the SOM Clinical Research Review Committee.	To reduce administrative burden	10/1/2020
Modified requirement to maintain <50% capacity and 200 square feet of space per person to requirement to maintain at least 150 square feet of space per person	To allow more flexibility within units	12/4/2020
Modified wellness check workflows for UNC employees to utilize EHS web screening portal.	To align with UNC HR and EHS policies	1/4/2021

HUMAN SUBJECTS RESEARCH

The Office of the Vice Chancellor for Research (OVCR) will govern decisions regarding reopening UNC Chapel Hill and research operations. On May 23, 2020, Dr. Magnuson announced that starting June 1, 2020, UNC will begin increasing the amount of research conducted on our campus in a phased, careful and sustainable way.

1

This document describes processes and guidelines for conducting human subjects research for investigators and study teams within the UNC School of Medicine. Human subjects research studies wishing to initiate or resume activities going forward will be subject to guidelines established by the SOM.

Any individual who can effectively conduct their work remotely should continue to work remotely so as not to place themselves or others at unnecessary risk.

These principles must be followed at all times by faculty, trainees and other staff involved in University research.

Please pay special attention to the requirements for wearing of face masks, eye protection, physical distancing, hygiene and cleaning practices while on campus.

Direct notice of updates and revisions to these guidelines will be disseminated via the CRSO listserv. If you would like to receive direct notice, you may subscribe to the CRSO listserv by clicking here. Updated documents and guidelines will also be posted on the CRSO website. If you have questions related to the guidelines outlined in this document or otherwise related to conducting human subjects research in the context of COVID-19, please contact crso@med.unc.edu.

What you will find in this document:

- 1. Direction and guidance for all on-campus research at UNC
- 2. SOM general information related to human subjects research in the context of COVID-19
- 3. Considerations for different types of human subjects research studies
- 4. Specific procedures and guidelines for research studies involving direct contact
- 5. General guidelines for worker safety
- 6. Special considerations for field-based research

If everyone working in a research facility uses the described precautions, we will minimize risk of COVID-19 transmission and maximize prevention and safety. OVCR is working on a testing and tracing plan in place for researchers across the university. Speak up to your supervisor, department chair or center director if you observe someone not following such precautions. Individuals may report non-compliance on the Ethics Point website or by calling the Hotline at (866) 294–8688. We are all responsible for workplace safety and ensuring the safety of participants.

1. Direction and Guidance for All On-Campus Research

Workplace Expectations

• Individuals who can effectively conduct their work remotely should continue to work remotely so as not to place themselves or others at unnecessary risk.

2

- Individuals who have been instructed to return to on-site work and wish to request a
 disability accommodation (e.g., for disabilities that place individuals at higher risk for
 severe illness from COVID-19) should contact the Equal Opportunity and Compliance
 Office at eoc@unc.edu.
- The University will provide guidance separately on requests for workplace flexibility for other situations, such as individuals who are at higher risk due to age or other factors, as set forth under CDC guidelines, or individuals who live with those who are high-risk.

Symptoms Monitoring

- All research faculty, employees and trainees must conduct a daily review of COVID-19 symptoms before returning to work. At this time, those symptoms include:
 - New muscle aches not related to another medical condition or another specific activity (e.g. due to physical exercise)?
 - Feeling like you may have a temperature of greater than 100.0°F?
 - o Sore throat not related to another medical condition (e.g. allergies)?
 - o New or worsening cough that is not related to another medical condition?
 - Shortness of breath that is not attributable to another medical condition?
 - Recent (<5 days) loss of smell and taste?
 - New onset of vomiting or diarrhea not related to another medical condition?
 - o Repeated shaking chills not related to another medical condition?
- Anyone who is experiencing any of the above symptom(s) must not come to campus.
- Persons exhibiting COVID-19 symptoms should contact their health care provider and act upon their instructions. UNC employees may also contact the University Employee Occupational Health Clinic (919–966–9119), and UNC students and post docs may contact UNC Campus Health (919–966–2281).

Any individual who has tested positive for COVID-19, who has been referred for testing or who is awaiting test results, may not come to work on campus for any reason until approved to do so by Employee Occupational Health or Campus Health.

Personal Safety Practices in the Workplace

Community Protective Equipment (CPE)

While in a University or UNC Health facility, all individuals must wear a University-approved face mask unless in a private and closed space (such as private office with the door closed). It is required to wear eye protection (in addition to a face mask) for all patient or participant encounters. It is recommended to wear eye in addition to a face mask in all small indoor areas with others (e.g. shared office, workroom, conference room). Acceptable face mask and eye protection options will be available at the UNC Environment Health & Safety website.

• Face Masks: The University will provide disposable face masks to research employees and trainees.

3

- These masks will be distributed to 'distribution coordinators' for each school, department, and/or center and these individuals are responsible for distribution to research personnel. Further details about mask distribution will be forthcoming.
- Each person working on campus will be provided one disposable face mask for use every two shifts or every two days of work. If an individual's work duties require more frequent disposal and replacement of masks, those needs will be accommodated.
- Individuals are not required to wear a face mask when working alone in a confined office space.
- These face masks may be re-used if it is not damaged, deformed, soiled, or contaminated. They should be placed inside a small clean paper bag marked with the user's name and stored away upon removal. To avoid bacterial growth, bags holding masks should not be tightly closed.
- These masks are not substitutes for N95 or other respirators. Lab workers enrolled in the Respiratory Protection program who are required to use N95 respirators for their duties must wear them for appropriate protection.
- Disposable face masks are not meant to be laundered. Persons using such masks must not touch their face after removing the mask and must wash their hands for at least 20 seconds with soap and warm water after removing the mask.
- Wear a mask on campus at all times. Please utilize a personal mask when coming and going and utilize a work mask when arriving to the research facility. Make sure to follow the steps in this video to ensure you wear your mask correctly. Do not remove the mask when going to the restroom (as indicated in the video).
- Pay attention to guidance on how long each mask should last and how to store it properly between wearings.
- UNC's <u>Department of Environment</u>, <u>Health and Safety</u> will provide instructions on how to properly care for and store masks.
- **Eye Protection:** Eye protection will reduce exposure to unknown COVID+ cases. Eye protection must be used in addition to a face for all participant/patient encounters. Eye protection in addition to a face mask is recommended in all small indoor spaces with others present (e.g. shared offices, workrooms, conference rooms). If you are exposed to people who subsequently become COVID+ (generally, displaying symptoms or testing positive within 3 days of the encounter), you will be forced to quarantine if you are not wearing eye protection in addition to a face mask.
 - Eye protection includes either a face shield, a face mask with attached face shield, or safety goggles or glasses that offer wrap around protection to the side of the eyes.
 - Eye protection does not include standard prescription glasses (even with side shields) or contact lenses.
 - Eye protection should be disinfected and reused:
 - Wipe eye protection with an EPA registered hospital disinfectant and let dry

4

- Rinse with water or alcohol if residue remains.
- Replace if broken or no longer able to be cleaned.
- Gloves: According to the CDC, gloves are not necessary for general use and do not replace good hand hygiene. Frequent hand washing is considered the best practice for common everyday tasks. Employees who will be interacting with the public or operating in a public setting where materials will be frequently exchanged are advised to wear disposable gloves. The University will provide gloves for these individuals. Instructions for how to remove and dispose of gloves properly will be available at the UNC
 Environment Health & Safety website.

Physical Distancing

Generally

- When on campus, all individuals must maintain appropriate physical distancing a minimum of 6 feet distance (150 square feet per person) – from others at all times while wearing a face mask.
- Assembling or convening in groups of greater than 10 people poses a significant risk of viral transmission and is not permitted.
- Individuals should avoid holding open exterior doors for others, as doing so would likely compromise the required physical distancing.

Common Areas and Meeting Rooms

- Common areas such as break rooms, offices, restrooms, elevators, and conference rooms should be used only while adhering to physical distancing guidance.
- Departments should remove or rearrange chairs and tables or add visual cue marks in meeting rooms to support physical distancing practices between attendees.
- All persons should wear a face mask while in common rooms (even if others are not present) to provide protection in the event other people walk in. If you anticipate close encounters with others, it is also recommended to wear eye protection.
- Room occupancy limits must be defined and clearly stated through appropriate signage for each laboratory. Personnel should confirm that the occupancy limit has not been reached before entering a lab or office.
- Where possible, meetings should be convened and conducted virtually. If a meeting
 must be held in person, physical distancing requirements apply and a minimum of 150
 square feet per person must be available at all times.

Meals

- Physical distancing of 6 feet should be observed at all times, including when eating or talking to someone in the workplace.
- Individuals are encouraged to eat meals outside, if possible.
- Meals should not be eaten in laboratory areas. They should be eaten alone or properly distanced from other individuals.

 If common areas such as break rooms and conference areas, etc. are used for meals, the person using them must wipe down surfaces using a 70% ethanol or equivalent solution.

Elevators

- Use of elevators is subject to the required physical distancing guidance.
- Wash your hands or use hand sanitizers upon departing an elevator.
- Use the stairs whenever possible and do not congregate in entrances, stairwells and elevator lobbies.

Hygiene and Cleaning

Hand Washing

- Although already a best practice for all researchers and trainees, during the pandemic it
 is imperative that hand washing become more frequent and more thorough. Hands
 should be washed for at least 20 seconds.
- Hands should be washed before interacting with a research participant and immediately after the session is over.
- Please view the CDC's "Five Steps to Wash Your Hands the Right Way."
- Also, please view the CDC video on handwashing.
- Provide guests the opportunity to wash hands if they are visiting you in your facility.
- If hand washing is not an available option, use hand sanitizer to disinfect hands.
- All individuals should thoroughly wash their hands or use provided hand sanitizer:
 - At least hourly,
 - Before entering or exiting buildings, laboratories or offices if they have been in a public space or near others, and
 - Before and after handling their face mask.
- Hand sanitizer will be made available throughout University facilities.

Cleaning and Sanitizing

- Research work may involve the frequent use of shared equipment. The University is
 increasing the cleaning frequency of common/public spaces; however, it is critical that
 all faculty, staff, and students share the responsibility of cleaning and sanitizing hightouch surfaces in their workspaces (e.g., light switches, doorknobs, etc.).
- Cleaning products and hand sanitizers will be provided by the University for this purpose. Supplies will be distributed to 'distribution coordinators' for each school, department, and/or center and these individuals are responsible for distribution to research personnel.
- Occupants of all research facilities should clean/wipe all high-touch surfaces when beginning work, at the end of the day, and at least four additional times daily.
- Shared equipment should be cleaned and wiped after each use.

Safety Monitoring

6

- Research facilities and buildings will be periodically monitored to ensure required safety measures are being practiced.
- If an employee is found to be out of compliance with the required practices, they will be counseled on the need for compliance with the required practices outlined in this guidance. Further instances of non-compliance may result in the employee being subject to disciplinary measures in accordance with applicable University policies.
- Compliance with required practices is a shared community responsibility.
- Individuals may report non-compliance by calling the Ethics Point Hotline at (866) 294–8688. Visit the Ethics Point website for additional information.

Visitor Policy

- Guests, visiting trainees, and other persons not affiliated with UNC should not visit University facilities or offices.
- Children are not permitted in University research facilities or offices during the COVID-19 event.
- Visitor restrictions do not apply to individuals participating in research studies being conducted in University facilities or to persons permitted on campus under the terms of a facility use agreement (FUA).

2. SOM general information related to human subjects research in the context of COVID-19

- Reopening of human subjects research in UNC facilities is dependent on the following:
 - o University policy allowing research to ramp up
 - OVCR approval to resume human subjects research activities involving direct participant contact
 - o University policy allowing non-essential employees back on campus
 - Personal Protective equipment (PPE) is plentiful so that both healthcare workers have adequate PPE and investigators and participants have a mask at all faceto-face interactions
 - Individuals follow the COVID-19 prevention rules of UNC Health and the medical director of the facility in which patient/participant-facing activities are occurring https://www.unchealthcare.org/coronavirus/
- Pertinent information relevant to human subjects research may be found:
 - COVID-19 Preparedness for Co-Workers and Providers (accessible only with a UNC Health domain account)
 https://unchcs.intranet.unchealthcare.org/Pages/2020/novel-coronavirus.aspx ¹
 - COVID-19 Information https://www.unchealthcare.org/coronavirus/
 - OVCR: https://research.unc.edu/covid-19/
 - o OHRE: https://research.unc.edu/2020/03/10/ohre-irb-covid-19-update/
 - SOM CRSO: https://www.med.unc.edu/crso/
- Note Concerning Travel and Parking: Travel for UNC business is currently restricted to North Carolina and is not permitted outside of the state at this time. The University will release more information about travel when we receive further guidelines from the UNC System and the State. Information on changes to University parking policies and public transit can be found at the University Transportation & Parking website.

3. Considerations for different types of human subjects research studies

The following are different types of human subjects research studies that could continue once UNC resumes activities:

- Non-interventional human subject research studies that do not include participant contact
 - Non-interventional human subject research studies that do not include participant contact can continue, e.g. population health studies that utilizes EHR data. If the work is conducted in UNC facilities, the PI is responsible that all the guidance herein is adhered to with regards to workplace safety and social distancing (see page 5).
- Non-interventional human subject research studies that include participant interactions and can be completed virtually
 - Non-interventional human subject research studies that include participant interactions but can be performed virtually can continue e.g. interviews handled

8

remotely. As above, if the work is conducted in UNC facilities, the PI is responsible that all the guidance herein is adhered to.

- Observational or interventional studies that include direct participant contact (in clinical or non-clinical spaces)
 - Studies that require face-to-face assessments or visits can continue, weighing risks and benefits for the participants. If the potential benefit of a face-to-face visit for a research participant exceeds the risk, visits are desirable. E.g., a patient who is doing well in a trial needs a blood test to monitor renal function or drug levels to be able to continue the study product safely. If it is the Pl's judgement that the potential benefit of the visit and continuation of the trial product exceeds the potential risk of the visit, the visit is allowed. The CDC recognizes nine high-risk groups for severe outcomes with COVID-19 such as those over age 65. As part of the ongoing consent process, research participants at high risk for severe outcomes should only be asked to participate if there are clear benefits to patients. They should understand the risks of breaking social distancing. Regardless of the location of the face-to-face visit (clinical versus non-clinical space), participants and research personnel must undergo the same screening procedures, and follow the same mask and visitor policies as described in the following pages and detailed in

https://unchcs.intranet.unchealthcare.org/Pages/2020/novel-coronavirus.aspx. 1

4. Specific procedures and guidelines for research studies involving direct contact

The following is a listing of required procedures for conducting human subjects research visits that involve direct contact with study participants. More details are available at https://unchcs.intranet.unchealthcare.org/Pages/2020/novel-coronavirus.aspx.1

- Consider the following measures to reduce direct contact, as applicable: drive through service where available for blood draw only visits rather than participant coming into the clinic/research site, use drive-by visits or mail to supply research participants with study medication/materials and use remote or virtual visits when possible.
- Advance wellness screenings for participants
 - o If the participant will attend an in-person study visit that is <u>not</u> in the context of an already scheduled UNC Health clinical visit (i.e. visit scheduled specifically for the purposes of the research activities), research personnel must perform telephone wellness screenings and confirm the participant's appointment no more than 24 hours prior to the scheduled visit.
 - o If the participant will attend an in-person study visit that will be completed in the context of an already scheduled UNC Health clinic visit (i.e. during a visit with a clinician, study activities will also occur), the study team may choose to omit the advance wellness screening, provided that the participant has already confirmed his/her willingness to meet with study personnel and/or continue with study

9

activities. If there is any uncertainty as to whether the participant will initiate or continue study participation at the scheduled clinical visit, research personnel should perform a telephone wellness screening and confirm the participant's appointment no more than 24 hours prior to the scheduled visit to reduce the chances of study personnel reporting to campus unnecessarily.

- Documentation of participant wellness screenings
 - Research personnel that have Epic access must document the completed screening in <u>Epic</u> for any research visits that occurs at any UNC Health facility.
 - For studies occurring in non-clinical spaces or for studies that do not utilize Epic, record of the participant wellness screening should be appropriately documented in the study records.
 - For patient, companion, and employee screenings in clinics not located at the UNC Medical Center, refer to the document "<u>UNC Medical Center Outpatient</u> <u>Clinic Screening at the Door</u>" ¹ workflow document.
- Research personnel will be subject to daily wellness checks prior to entering any UNC or UNC Health facility. For UNC employees, this should be completed via the UNC EHS COVID-19 Wellness Check portal. Employees of UNC Health should complete either the UNC Medical Center screening or the UNC Faculty Physicians screening. Individual clinics/units may require additional screenings. Any individuals found to be positive for symptoms consistent with COVID-19 will immediately leave the work environment (not enter the facility) and be advised to contact Occupational Health. As much as possible, employees should recognize symptoms in advance and not report to the workplace.
- Research personnel must follow UNC Health's Mask policy regarding proper usage and storage of <u>masks for employees</u>¹, and <u>masks for participants and guests</u>¹.
- Individuals must wear eye protection in addition to a face mask for all participant/patient encounters.
- It is recommended for individuals to wear eye protection in addition to a face mask when in close proximity to others (e.g. shared office space, workrooms, etc.)
- Research personnel must be aware of and follow <u>UNC Health's COVID-19 Visitor</u>¹
 policy to determine who is permitted to attend visits with participants; all visitors must
 complete a prescreening wellness check prior to and on arrival to the clinic or
 designated research visit location.
- Participants will be rescreened upon arrival to a UNC Health facility by front desk staff.
 Research personnel must rescreen participants upon arrival for visits that will occur in
 non-clinical spaces before the visit begins (no symptoms, no fever, etc.) and
 appropriately document the screening in the study records. Any participant who fails
 rescreening should be immediately masked and isolated in a private room. Clinical
 study personnel should be contacted and follow recommendations from Infection
 Prevention regarding referral for testing. The UNC patient COVID-19 Helpline number is
 888-850-2684.

Process to initiate human subjects research studies involving direct patient/participant contact:

- The study PI must review and carefully consider the expected benefits vs. risks for study participants to determine if the study should continue with direct contact visits or assessments (continued participation or recruitment) in the context of COVID-19. Any study activities that can be completed remotely, should be (as approved by the IRB) in order to limit the amount of time spent interacting directly.
- As part of the ongoing consent process, the participant should also understand the
 potential harms of visiting a health care facility at this time and agree willingly to the
 visit. For example, the risk to a frail elder with a history of cancer and heart disease may
 be greater by coming to a study visit than the potential benefit from the care provided in
 the context of the study. Each participant should be given the chance to discuss the
 expected risks and benefits and make an informed decision regarding participation,
 along with support from the study team.
- All studies will be required to provide an information sheet to subjects (unless enrollment is due to a COVID diagnosis and treatment), that outlines the risk of COVID-19 and the risk mitigation strategy that has been put in place. This is an information sheet only and does not need to be signed, however the conversation with participant, the risk analysis for subject by subject continuation, and the outcome of the discussion should be documented in the subject's research record (COVID-19 Participant Discussion Documentation Template). The information sheet and approval letter will be posted on the OHRE website.
 - o Provided that the consent template is used verbatim, except where "X's" have been inserted to allow for study specific information, then the use of this template does not need to be submitted to the IRB for approval. Please retain a copy of the "COVID Information Sheet Approval Letter" in your study files. If you would like to make changes to this information sheet, outside the "X's" for general information, either to add, remove language, or your procedures for risk mitigation are different, this requires the submission of a modification including a risk analysis to the IRB.
 - o If you are resuming research activities after June 1, 2020 and were not provided permission previously by the OVCR's office and need to make changes to this IRB-approved COVID Information Sheet, you may not begin activities until those changes have been submitted, reviewed, and approved by the IRB. If you were previously given permission by the OVCR's office as your study provided direct benefit, you may continue, however the COVID information sheet above should be used until the modification altering language is approved, if alteration of language is necessary.
 - This information sheet is institution-wide and reflects UNC's guidance and OVCR's institutional policy, this information sheet, or another approved by the UNC-IRB should be used for all research being conducted by UNC-Chapel Hill regardless of IRB of record. If you have questions about this please reach out to John Roberts the Associate Director of Regulatory Affairs and Compliance.

General guidance for human subjects research studies involving direct patient/participant contact:

- All materials used during study visits should be appropriately cleaned and sanitized before and after each study visit (e.g. chairs, surfaces, exam tables, clipboards, pens, blood pressure cuffs, exercise equipment, etc.)
- Practice good hand hygiene before and after each patient encounter and before preparing a room for a research participant encounter (as always!):
 - Wash hands often with soap and warm water for at least 20 seconds.
 - If soap and warm water are not readily available, use an alcohol-based hand sanitizer that contains at least 60% alcohol.
- Increase the frequency of cleaning and disinfecting, **focusing on high-touch surfaces.** We have developed a <u>template checklist</u> that you may choose to utilize to ensure you are considering all guidelines and recommended procedures prior to conducting a face-to-face visit with research participants.

5. General guidelines for worker safety

General guidelines to ensure worker safety, adapted from laboratory-based research recommendations, follow. These should be stringently followed by research personnel engaged in human subjects research.

General SOM guidelines for COVID-19 prevention while at work.

Once we are allowed to resume operations at least partially, work guidelines outlined below will allow researchers and others to maximize the safety of everyone who comes to campus to work and to reduce the spread of illness throughout our community. It is very important to emphasize the importance of following these guidelines to not jeopardize the ability of our units to conduct research. There likely will be a second wave of the epidemic. The situation will need to be monitored carefully and guidelines are expected to adapt in accordance with changing information. The Office of the Vice Chancellor for Research is currently developing a voluntary COVID- 19 testing program and plans to provide a voluntary contact tracing mobile app as additional measures beyond the required practices detailed here. More details about these programs will be provided when they are available.

All UNC COVID-19 related updates can be found at https://www.unc.edu/coronavirus/

All UNC research updates related to COVID-19 can be found at https://research.unc.edu/covid-19/

In order to mitigate virus spreading, the guiding principle for safe workplace operations will be social distancing. To help ensure this principle, all conduct of allowable research must minimize the number of researchers in the facilities at any one time. Thus, our guidelines are designed with the goal of maintaining at least 150 square feet of space for every individual at any one time.

Anyone who can work from home should continue to work from home.

Please establish coordinated work schedules for your research personnel to reduce and maintain workspace of at least 150 square feet per person.

To facilitate coordination and enforcement of the guidelines, each PI should make an operational plan for their research space and send it to their chair or center director depending on the unit that manages their space.

Principal Investigators are responsible for ensuring conscientious and consistent adherence to schedules and guidelines.

Employees and Trainees should not work alone, especially after hours. Plans should be in place for at least two people to work together, while following appropriate distancing guidelines.

Further guidance is expected from main campus regarding Parking on campus. Please contact the Parking office if you have questions.

Guidelines for personnel safety

- **Daily wellness check** Perform daily checks of wellness and document the wellness screening in the appropriate web system
 - o UNC Employees: https://ehs.cloudapps.unc.edu/UEOHC/covid19wellness
 - o UNC Health Employees: https://ha.healthawareservices.com/ra/survey/4712
 - o UNC Health Faculty Physicians: https://ha.healthawareservices.com/ra/survey/4711
- Never come to work at a research facility if you are experiencing any symptoms of infection. (See symptoms monitoring on page 2)
- If you come to work and start showing any possible symptoms of illness, you must leave the workplace and inform your healthcare provider, UNC Occupational Health and Safety at 919-966-9119 (https://ehs.unc.edu/ueohc/), and PI or supervisor. UNC students and post docs may contact UNC Campus Health (919–966–2281).
- If you have been referred for testing, or are awaiting results, you must also alert your PI and you must not come to work on campus for any reason until approved to do so by Employee Occupational Health or Campus Health.
- If you have close or prolonged contact with anyone who is SARS-CoV2/COVID-19
 positive or under investigation for potential exposure, contact <u>UNC Occupational</u>
 <u>Health and Safety</u> or <u>UNC Campus Health</u> for guidance and approval before going to work.
- Wear a mask on campus at all times. Please utilize a personal mask when coming and going and utilize a work mask when arriving to the research facility. Make sure to follow the steps in this video to ensure you wear your mask correctly. Do not remove the mask when going to the restroom (as indicated in the video). Pay attention to guidance on how long each mask should last and how to store it properly between wearings.
- Personnel must wear face mask and eye protection for all encounters with research participants and patients.

- It is recommended to wear eye protection and a mask if you are in a small indoor area
 with others like shared offices or workrooms. If you are exposed to people who
 subsequently become COVID+ (developing symptoms or testing positive within 3 days
 of encounter), you will be forced to quarantine if you are not wearing eye protection in
 addition to a face mask.
- Assume everyone around you is infected, including yourself, and use appropriate
 precautions, including washing your hands often and avoiding touching your face.
 Transmission can occur from people with no symptoms.
- Please note that that the CDC guidance indicates that the virus does not spread easily via contaminated surfaces, and shoes and clothing would not be a likely route of transmission. However, you may choose to:
 - (i) Remove shoes worn outside including when working in a laboratory/facility when you return to your home.
 - (ii) Remove clothing worn in the workplace when you return to your home. Limit workplace presence to periods that are only as long as necessary to complete your experiment. Minimize time around other people.
- Visitors, shadowing students, visiting trainees, or guests are not allowed on campus in labs or research facilities and offices, unless specifically approved by the Vice Chancellor for Research.
- Study monitors may return to campus after June 1 assuming that they undergo
 wellness checks as described for research participants, they agree to abide by all
 direction and guidance for all on-campus research at UNC, and you have adequate
 facilities to accommodate their presence while maintaining social distancing.
- Please do not bring family members into the workplace to minimize the chance of people being infected.
- Be responsible and safe in the community (stores, offices, etc.) to avoid contracting the virus.

Guidelines for operating a safe work environment A minimum of 150 square feet of space per person must be available at all times.

- Create a work schedule for your research space and adhere to it. This schedule should minimize the number of people in each work room at any one time. A shared Google calendar or another online tool should be used to help coordinate everyone's schedule.
 - Each PI should make an operational plan for their lab and send it to their chair or center director depending on the unit that manages their lab space.
 - Use an online calendar to signify who is present in the research facility at any given time
 - Coordinate with neighboring research units for open concept buildings, particularly when there are shared small rooms such as communal offices, cold rooms, tissue culture, etc.
 - Wear a mask when on campus.

- To reduce chances of accidental exposure and required quarantining, it is recommended to wear eye protection in addition to a face mask when in small indoor space with others (e.g. shared office space, clinic rooms, waiting rooms, etc.)
- Disinfect shared materials as described below.
- Distribute a list of duties to be performed by personnel, with location and designated time of day for indicated duties.
- Continue to have virtual meetings. Time on site should be only for work that can <u>only</u> be done on site.
- Stagger break times to minimize contact between people in rooms used for eating or drinking, set the schedule to maximize work efficiency and minimize downtime. Be sure to disinfect surfaces such as tables and chairs before and after using such facilities. Guidelines for disinfectants that work against coronavirus can be found at the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cleaning-disinfection.html
 - Cups, mugs, plates, and silverware must be washed with soap before and after use.
 - Wash your hands before and after using a break room.

2. Create safe spaces to maintain at least 6 feet between researchers at all times

- Post room maps with maximum room/bay occupancy to maintain social distancing (see examples below).
- Small, narrow facilities on the order of 100-150 square feet can only accommodate one person at a time.
- Workspaces larger than 150 square feet can possibly accommodate more personnel but keep the number to a minimum. Use common sense. If you cannot maintain at least 6 feet of social distance, revise the schedule and/or reconfigure the room.
- Move equipment to create at least 6 feet between the operators and to reduce the number of narrow spaces in rooms and hallways where researchers must pass each other
- Consider marking the floors with tape to indicate distance from desks or benches.
- Please carefully consider activities that must occur in clinical exam rooms, as these are typically limited in size (often less than 100 square feet)
 - o Limit the number of people in the exam room to only essential individuals
 - o Limit time spent in the exam room as much as possible
 - o If a larger exam room or procedure room is available for research assessments that require more than 2 individuals, consider utilizing that larger space

3. Create a plan for safe practices in the workplace.

 Wear your own mask at all times. Masks can help protect others by containing respiratory droplets when the mask wearer speaks, sneezes or coughs. The UNC SOM is distributing surgical masks each week for SOM research personnel. Face coverings must not interfere with PPE, e.g. eye shields, required for safety and must be compatible with all safety requirements. Pay attention to guidance on how long

each mask should last and how to properly store it between wearings. Workers may remove mask while in a private office with door closed.

- Perform hand hygiene before and after using any mask or face covering.
- Never touch the outside of the mask always assume the outside-facing side is dirty. To reduce chances of accidental exposure and required quarantining, it is recommended to wear eye protection in addition to a face mask when in small indoor space with others (e.g. shared office space, clinic rooms, waiting rooms, etc.)
- Researchers should wash their hands with soap or use hand sanitizer upon entering and before leaving the workplace and touching shared accessory devices like phones (use speakerphone if possible), computer keyboards etc.
- Each researcher will have their own set of any tools (please label with your name or initials) that are used very frequently, including stethoscopes, pipettes, reagent bottles, laboratory notebooks, staplers and writing instruments.
- Gloves and disposable towels should be used when handling common reagent bottles, laboratory equipment, common computers, and cabinet handles.
- Door handles should be wiped or sprayed with 70% ethanol (or other EPA <u>approved disinfectant</u>) at least twice daily but may require cleaning and disinfecting more often throughout the day depending on usage and foot traffic in the area. Ideally post a log sheet for each workspace to document daily disinfection.
- Public facilities are cleaned by UNC housekeeping staff but please help them out.
 Please have research staff wipe down common area door handles at least once a
 day, preferably when first entering space in the morning and when leaving the space
 in the evening. Reopening guidance for cleaning and disinfecting in the workplace
 can be found on the CDC website at https://www.cdc.gov/coronavirus/2019-ncov/community/reopen-guidance.html.

4. Create a plan for shared equipment. All shared equipment must be disinfected before and after each use.

- Wear disposable gloves while cleaning and disinfecting. Discard gloves after each use. Clean hands immediately after gloves are removed.
- Follow the EPA guidelines above to clean hard, non-porous surfaces and porous surfaces, as appropriate.
- Gowns or aprons are recommended to protect personal clothing.
- Wear eye protection when there is a potential for splash or splatter to the face.
- Special care should be taken to disinfect equipment that normally makes direct physical contact with human skin, which includes eyepieces for microscopes, keyboards, touch pads, freezer door handles, etc.
- Use disposable tissues, paper towels, Kimwipes, etc. to touch surfaces that cannot be disinfected and when gloves are not available.
- Use disposable towels to turn off sink faucets after hand washing to avoid recontaminating hands.

5. Create a plan for interactions with others outside your immediate workgroup.

• No more than one person may enter an elevator at a time unless there is COVID-

16

- specific signage otherwise (e.g., UNCH hospitals). Please use the stairs whenever possible and do not congregate in entrances, stairwells and elevator lobbies.
- No more than one person should occupy common/highly frequented areas such as break rooms, offices, bathrooms, and conference rooms at any given time.
- Contact with other work groups should preferably be through phone calls or email/text messaging except in cases of extreme emergency.
- Transfer of items should be arranged by leaving them in a designated area rather than handing them over in person.
- Use of shared facilities and other groups' equipment should be pre-arranged in order to avoid accidental contact.
- Use precautions when entering a restroom or other shared use facility. Call out to assess occupancy. Use a paper towel or Kimwipe to touch door handles and faucets and wash your hands upon entering and leaving the restroom.
- Create a plan for a possible or confirmed case of COVID19 among personnel in a workspace. Notify UNC Occupational Health and Safety immediately (https://ehs.unc.edu/ueohc/) at 919-966-9119.

7. Enhanced cleaning for prevention

- General guidance: Full guidance available on the <u>CDC website</u>.
 - Increase the frequency of cleaning and disinfecting, focusing on high-touch surfaces.
 - Practice good hand hygiene after cleaning (and always!):
 - Wash hands often with soap and warm water for at least 20 seconds.
 - If soap and warm water are not readily available, use an alcohol-based hand sanitizer that contains at least 60% alcohol.

Safety guidelines during cleaning and disinfection:

- Wear disposable gloves, when available, while cleaning and disinfecting.
 Gloves should be discarded after each use. Clean hands immediately after gloves are removed.
- o Wear eye protection when there is a potential for splash or splatter to the face.
- o Gowns or aprons are recommended to protect personal clothing.
- Store chemicals in labeled, closed containers. Store them in a manner that prevents tipping or spilling.

Cleaning and disinfection of surfaces:

- Clean surfaces and objects that are visibly soiled first. If surfaces are dirty to sight or touch, they should be cleaned using a detergent or soap and water prior to disinfection.
- Clean and disinfect affected surfaces as soon as possible after a known exposure to a person with respiratory symptoms (such as coughing/sneezing).
- Use an <u>EPA-registered disinfectant</u> for use against COVID-19. Refer to the list of products pre-approved for use against SARS-CoV-2. Readily available

- products include 70% ethanol and 10% bleach. Allow at least 2 minutes of contact time before wiping.
- Follow the manufacturer's instructions for safe and effective use of all cleaning and disinfection products (e.g., dilution concentration, application method and contact time, required ventilation, and use of personal protective equipment).
- Consult manufacturer recommendations on cleaning products appropriate for electronics. If no guidance is available, consider the use of alcohol-based wipes or spray containing at least 70% alcohol. Use of alcohol-based products may reduce risk of damage to sensitive machine components. Whenever possible, consider using wipeable covers for electronics.

If everyone working in a research facility uses the described precautions, we will minimize risk of COVID-19 transmission and maximize prevention and safety. Speak up to your supervisor, department chair or center director if you observe someone not following such precautions. We are all responsible for workplace safety and ensuring the safety of participants.

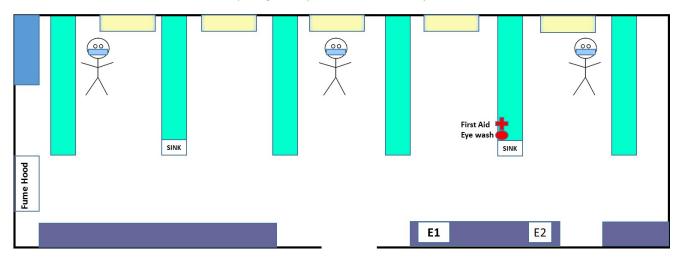
Please note that the following maps serve as a guideline only. <u>We cannot envision every circumstance.</u>

We encourage you to draw your own map and tailor it to your own spaces and rooms and distribute to your research personnel.

Always exhibit your best judgement, and if you have any doubts please consult with your department chair or center director.

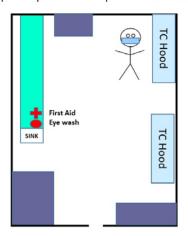
Some key documents from the UNC Health websites are replicated on CRSO website for those without UNCHCS intranet access https://www.med.unc.edu/crso/unc-healthcare-guidelines-for-covid-19/

Spacing of lab personnel in laboratory room



- · Guideline is to keep at least 6 feet distance between 2 people and everyone wears a mask
- · Work in shifts so that not all lab personnel are in lab at the same time (use online calendar for scheduling times)
- Lab = 1 person (with mask) per every 150-200 sq ft spaced out or 1 person per bay depending on lab configurement
- Due to proximity of Equipment 1 (E1) and Equipment 2 (E2) only one person at a time can use either E1 or E2
- Important to clean all common areas and pieces of equipment after each use

1 person per 100-200 sq ft BSL2 TC room*



1 person per warm room/cold room

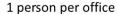


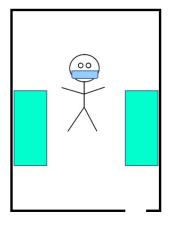
1 person per 100-200 sq ft equipment room

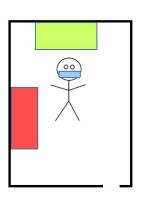


- · Guideline is to keep at least 6 feet distance between 2 people and everyone wears a mask
- Each room = 1 person (with mask) per every 150-200 sq ft
- *One person per 100-200 sq ft BSL2 tissue culture (TC) room. People who work in BSL2 TC rooms either have to restrict the
 personnel to 1 person per 150-200 sq ft room, or adopt BSL2+ or BSL3 operating procedures which includes additional PPE.
- · Important to clean all common areas and pieces of equipment after use

1 person per 150-200 sq ft break room







- Guideline is to keep at least 6 feet distance between 2 people and everyone wears a mask
- Each room = 1 person (with mask) per every 150-200 sq ft
- · Important to clean all common areas after use
- · 1 person per office

6. Special considerations for field-based research

- Field-based and community-based participatory research may continue if permitted by the University and by the School's Research Dean and if the required safety measures in the OVCR guidance can be followed.
- Travel for UNC business is currently restricted to North Carolina and is not permitted outside of the state at this time. The University will release more information about travel when it receives further guidelines from the UNC System and the State.
- When traveling by vehicle, no more than two people should occupy a standard car at a time, and each should always be wearing a University-provided mask and eye protection. If possible, windows should be open to allow for a constant supply of fresh air.
- When interacting with individuals in the field, University-provided masks should always be worn, and gloves and eye protection should be used if directly interacting with or exchanging items with another individual. Researchers must provide masks, eye protection, and gloves (if direct interaction or exchange of items is required) for study subjects.
- Research that involves participants of 10 or fewer individuals in a group, such as a
 focus group, is allowed. Seating should be arranged to allow 6 feet between group
 members, and all focus group participants must wear face masks.
- Physical distancing (minimum 6 feet distance while wearing a mask) is required.
- Researchers must adhere to all safety guidelines provided by the research site, including but not limited to, use of additional protective personal equipment, if required.
- If research participants are provided data collection equipment (e.g., wearable devices)
 for use in the field site, that equipment must be thoroughly cleaned and sanitized prior
 to release to and following return from each participant's use. Cleaning supplies and
 directions for using those supplies with the data collection equipment must be provided
 to participants for their own use.
- If research involves travel or overnights, accommodation and meals should allow for adequate physical distancing (6 feet or more) wherever feasible.